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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/628,843

07/28/2003

Leonard S. Schultz

6971.02

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7590

11/28/2007

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EXAMINER

YABUT, DIANE D

ART UNIT

PAPER NUMBER

3734

MAIL DATE

DELIVERY MODE

11/28/2007

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

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Office Action Summary	Application No. 10/628,843	Applicant(s) SCHULTZ, LEONARD S.	
	Examiner Diane Yabut	Art Unit 3734	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 September 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 29-38 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 29-38 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
- 1. ☐ Certified copies of the priority documents have been received.
 - 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 - 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413)
Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08)
Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

This action is in response to applicant's amendment received on 09/07/2007.

The examiner acknowledges the amendments made to the claims.

Claim Rejections - 35 USC § 103

1. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

2. Claims 29-32, 34-35, and 38 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Zdeblick** (U.S. Patent No. **5,984,967**) in view of **Conston** (U.S. Patent No. **5,456,693**).

Claims 29-32, 34-35, and 38: Zdeblick discloses providing a plug or plugging means **10** defining a plurality of openings and being configured and dimensioned to occlude flow through a lumen and inserting said plug into the body lumen with the plugging means entering the lumen first, advancing said device through said body lumen using a delivery instrument, or delivery means, **76** detachably coupled to the plug for moving to a target site or selected location **E** (Figures 2 and 13(c)-13(d)) and injecting a biological bonding agent or biphasic material ("calcium phosphate composition") into the delivery means for being moved through the openings, wherein the plurality of openings are generally arranged to allow the biological bonding agent or biphasic material to extrude through the plurality of openings to the interior wall of the lumen for binding the plug to

the interior of the lumen to fix said plugging means relative to the interior wall of said body lumen, detaching the delivery means from said plugging means, and withdrawing said delivery means from said body lumen, leaving said plugging means inside said body lumen (col. 1, line 40 to col. 11, line 5).

Zdeblick discloses the claimed device except for the plug being configured and dimensioned to substantially completely occlude flow through a lumen.

Conston teaches a plug being configured and dimensioned to substantially completely occlude flow through a lumen (see abstract). It would have been obvious to one of ordinary skill in the art at the time of invention to modify the fusion device of Zdeblick (wherein "fusion" may be considered a form of occlusion) by configuring and dimensioning the plug to substantially completely occlude flow through a body lumen, such as a vessel, as taught by Conston, since it was well known in the art to effectively block body lumens, particularly blood vessels, for a variety of situations such as controlling bleeding in the brain or renal embolization, and also using embolization plugs that also may deliver agents to the lumen (col. 1, lines 13-22 and 50-61).

3. Claims 33 and 36-37 are rejected under 35 U.S.C. 103(a) as being unpatentable over **Zdeblick** (U.S. Patent No. **5,984,967**) and **Conston** (U.S. Patent No. **5,456,693**), as applied to Claims 29 and 34 above, and further in view of **Wallace** (U.S. Patent No. **6,585,754**).

Claims 33 and 36-37: Zdeblick and Conston disclose the claimed device except for the bonding agent or biphasic material comprising a shape memory material. Conston does teach the use of polyurethane with memory characteristics (col. 3, lines 24-37).

Wallace teaches a vaso-occlusive member and the use of biphasic material and biosorbable material (col. 4, lines 48-57) and shape memory material (col. 4, lines 41-45), wherein the biosorbable and shape memory materials are biphasic. Wallace teaches that the use of these materials encourages greater tissue ingrowth, and therefore more stable occlusions (col. 4, lines 15-17). It would have been obvious to one of ordinary skill in the art to have the bonding agent comprise shape memory material, as taught by Wallace, to Zdeblick and Conston, in order to provide greater tissue ingrowth and therefore a more stable occlusion in the body lumen.

Response to Arguments

Applicant's arguments with respect to claims 29-37 have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

3. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Diane Yabut whose telephone number is (571) 272-6831. The examiner can normally be reached on M-F: 9AM-4PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Hayes can be reached on (571) 272-4959. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

DY

A handwritten signature in black ink, appearing to read "MJ Hayes", with a stylized flourish at the end.

MICHAEL J. HAYES
SUPERVISORY PATENT EXAMINER